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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,599	02/20/2002	Cornelia Anna Mundt	GJE-87	9658

23557 7590 12/16/2004

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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/081,599	Applicant(s) MUNDT ET AL.	
	Examiner Celine X Qian Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 5-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-15 are pending in the application. Claims 5-14 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-4 and 15 are currently under examination.

This office action is in response to the Amendment filed on 9/24/04.

#### ***Response to Amendment***

The rejection of claims 1-4 and 15 under 35 U.S.C. 112 2<sup>nd</sup> paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 1-4 under 35 U.S.C 102 (b) has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 1-4 and 15 under 35 U.S.C.112 1<sup>st</sup> paragraph is maintained for reasons set forth of the record mailed on 3/24/04 and further discussed below.

#### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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In response to this rejection, Applicants argue that the amended claims clarify that the artificial chromosomes of the subject invention comprise a region that is not only between C $\delta$  and C $\gamma$ 3, but also regulates immunoglobulin gene activation during lymphoid development. Applicants further assert that the specification discloses examples of such sequences as well as an assay for readily identifying this activity. Applicants thus conclude that such teaching is sufficient for one skilled in the art to make and use the claimed invention without undue experimentation.

These arguments have been fully considered but deemed unpersuasive. As discussed in the previous office action, the written description requirement requires the specification to disclose a representative number of species by their complete structure or other identifying characteristics. Although the claims as amended recite a function for the claimed polynucleotide within the artificial chromosome, the specification has not described the complete structure for the claimed genus of the artificial chromosome. As discussed in the previous office action, the specification only discloses a specific 1.3kb region between C $\delta$  and C $\gamma$ 3 of the human IgH locus has enhancer function in early lymphoid development. The region between C $\delta$  and C $\gamma$ 3 is 52kb. The claimed genus of a polynucleotide sequence between C $\delta$  and C $\gamma$ 3 of the human IgH locus encompasses a large number of nucleic acid sequences of various sizes that may or may not have the claimed function. Although the specification teaches assays for identifying such polynucleotides, it does not constitute the structural requirement for the statute. Whether one of skill in the art can make and use the claimed invention without undue experimentation is not relevant for satisfying the written description requirement of the claimed invention. A structural and functional relationship must be taught by the instant specification or prior art to

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satisfy the written description requirement. Since the specification fails to describe the claimed invention by their complete structure or identifying characteristics, the written description requirement is not met. Therefore, this rejection is maintained.

The claims will be allowable if amended to directed to the 1.3kb fragment.

Applicants indicate in the first page of the Remarks that claims 5-14 are cancelled (see 2<sup>nd</sup> paragraph). However, the claims set still indicates these claims as withdrawn. Applicants are reminded to clarify the status of the pending claims in the next response.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

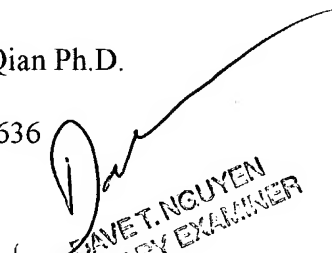
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.  
Examiner  
Art Unit 1636



DAVE T. NGUYEN  
PRIMARY EXAMINER